

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0220]

DDM

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Certifier	A. Corbin

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Administrative Detention and Banned Medical Devices.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

The Food and Drug Administration (FDA) has the statutory authority under section 304(g) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 334(g)), where officers or employees duly designated by the Secretary (FDA investigators) may detain devices during establishment inspections which are believed to be adulterated or misbranded. On March 9, 1979, FDA issued, under § 800.55 (21 CFR 800.55), a final regulation on Administrative Detention Procedures (44 FR 13234), under section 304(g) of the act, which includes certain reporting requirements (§ 800.55(g)(1) and (g)(2)) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception, or unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. The final regulation for Banned Devices (44 FR 29221), which issued on May 18, 1979 (part 895 (21 CFR part 895)), contained certain reporting requirements (§§ 895.21(d) and 895.22(a)).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
895.21(d) and 895.22(a)	26	1	26	16	416
Total					441

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

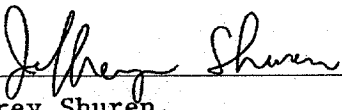
TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
800.55(k)	1	1	1	20	20

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with the last firm whose devices had been detained. Historically, FDA has had very few or no annual responses for this information collection.

Dated: 6-1-06
June 1, 2006.


Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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